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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/935,717	09/23/1997	MICHAEL CATT	241939	8965

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/16/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/935,717

Applicant(s)

Catt

Examiner

Portner

Art Unit

1645

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 13, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-10 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

Claim 1 has been amended.

Claims 1 and 5-10 are pending.

## **CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2001, has been entered.

### ***Rejections Maintained***

2. Claims 1, 5-10 remain rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103 as obvious over Catt et al WO 95/13531 for reasons of record in papers 2,8 and 11.

3. Claims 1, 5-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al (US Pat. 5,526,120, filing date September 8, 1994) for reasons of record, papers 2,8 and 11.

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***Response to Arguments***

4. Applicant's arguments filed November 13, 2001 have been fully considered but they are not persuasive.

5. In response to the Advisory Action dated September 11, 2001, Applicant asserts that the newly submitted claim limitations obviate the applied prior art. The examiner's advisory action is summarized by stating "the Examiner indicated that the applicants' claims differed more in the sense of method than structure."

6. It is the position of the examiner that the arguments made of record addressed the structural components of the claimed device, specifically the device of the instant Application and the device of Catt et al (WO95/13531) and Jina et al (US Pat. 5,526,120, filing date September 8, 1994).

The examiner rejected claims 1 and 5-10 through application of Catt et al (WO95/13531) reference as anticipating under 35 U.S.C. 102 or in the alternative obvious under 35 U.S.C. 103 and applied Jina et al (US Pat. 5,526,120, filing date September 8, 1994) to claims 1 and 5-10, as being obvious under 35 U.S.C. 103(a).

(Catt et al arguments made by the examiner) Based upon structural comparisons, the relationship of the test strip and the reading device is one in which the spacial relationship is interlocking to insure that a predetermined spacial relationship relative to said reading means is maintained.

When the device is received into the reading device the receiving means includes an actuating

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means which is triggered (claim 13) by the receipt of the device and the actuating means causing the reading of the detection zone to be initiated.

The switch actuating means is taught to comprise a fixed projecting portion and a displaceable projecting portion. The casing also comprises a recessed contact portion to accommodate the fixed projecting portion of the switch actuating means.

It is the position of the examiner that Catt et al disclose an apparatus that includes an actuating means that is triggered by the insertion of the assay device, and upon correct insertion, the actuating means causes the reading of the detection zone to be initiated (claim 13, page 34, lines 29-33). The “a portion of the assay device” argued by Applicant is not clearly defined in the claims. What is this portion that distinguishes the claimed invention from the prior art? The portion referred to appears to be the apparatus of the prior art.

The prior art apparatus in figures 4a-4b, 5, 6 and 7 shows various structural features that define a lock and key relationship between the apparatus and the test strip inserted.

The relationship of the test strip and the reading device is one in which the spacial relationship is interlocking to insure that a predetermined spacial relationship relative to said reading means is maintained (see page 23, lines 30-35). When the device is received into the reading device the receiving means includes an actuating means which is triggered (claim 13) by the receipt of the device and the actuating means causing the reading of the detection zone to be initiated.

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The switch actuating means is taught to comprise a fixed projecting portion and a displaceable projecting portion. The casing also comprises a recessed contact portion to accommodate the fixed projecting portion of the switch actuating means.

Thus the reading is enabled only by contact and displacement action of test strip with the reading device. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Catt.

Thus the reading is enabled only by contact and displacement action of test strip with the reading device. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Catt. Therefore the reference inherently anticipates, or in the alternative obviates the now claimed invention for reasons of record in paper numbers 11, 8 and 2.

(Jina et al arguments made by the examiner) Jina et al show a test strip with an asymmetrical end which insures the correct insertion for measuring for an analyte in a liquid sample. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures).

Thus the reading is enabled only by contact and displacement action of test strip with the reading device. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Jina.

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Jina et al show a test strip with an asymmetrical end which insures the correct insertion for measuring for an analyte in a liquid sample. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte.

The closed electrical circuit is a type of switch actuating means that is completed only upon correct receipt of the assay device. (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures 7 and 8). Thus the reading is enabled only by contact and interaction of the test strip with the reading device. The test strip is displaceable, but when in a lock and key relationship, the circuit is completed, switch actuation achieved and assay results read. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Jina.

With respect to formulation of the apparatus and test strip into kit form, the apparatus and test strip are taught to be used for medical measurement of blood analytes (see col. 1, lines 32-33 and col. 5, lines 34-35). Kits are known to provide means for commercialization, standardization and distribution of a product to the end user. The rejection of claims 1, 5-10 remain rejected for reasons of record in paper number 11, paragraphs 7-8, paper number 8 and paper number 2.

7. It was further asserted that "applicant's specific structural arrangement to accomplish the indicated results, i.e. to avoid a premature or incorrect reading of the results by triggering the

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reading means before the assay device is correctly positioned in the receiving means" is not disclosed or suggested in the applied references.

8. It is the position of the examiner, that structurally the devices of the prior art are so arranged to insure the correct reading of test results based upon the lock and key structural shapes of the assay device and the reading device (see figures of both references). The "indicated results" would be accomplished by the device of Catt et al, as well as the device of Jina because the specific lock and key structural arrangement of both devices provide for obtaining readings and results that are correct based upon the correct positioning of the assay device in the reading device, thus avoiding incorrect readings. What the structural components are of the instant device that define over the applied prior art are not claimed. The prior art references are maintained.

### ***Conclusion***

9. This is a non-final action.

10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

April 8, 2002

*LZf*  
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